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REMARKS

Claims 49-56, 60, 69-72, 77, 78, and 108 were pending, and were rejected by the Examiner. Claims 49, 77, and 78 have been canceled. Claim 50 has been amended to recite an isolated nucleic acid having a sequence about 4,609 to about 12,571 nucleotides in length, wherein the sequence includes: (a) a primer binding site; (b) a reverse transcriptase coding sequence positioned 3' to the primer binding site, and (c) at least one long terminal repeat positioned 5' to the primer binding site or 3' to the reverse transcriptase coding sequence. The primer binding site recited in amended claim 50 is selected from the group consisting of (i) a sequence having at least 95% identity to the sequence shown in SEQ ID NO:1 or SEQ ID NO:2; and (ii) the sequence shown in SEQ ID NO:1 or SEQ ID NO:2. In addition, claim 69 has been amended to coincide with the amendment to claim 50, and recites that the reverse transcriptase coding sequence is selected from the group consisting of: (a) a nucleic acid sequence having at least 70% identity to the sequence shown in SEQ ID NO:11; (b) a nucleic acid having the sequence shown in SEQ ID NO:11; (c) a nucleic acid sequence that encodes an amino acid sequence having at least 79% identity to the sequence shown in SEQ ID NO:12; and (d) a nucleic acid sequence that encodes the amino acid sequence shown in SEQ ID NO:12. Support for these amendments can be found in, for example, the nucleotide sequences set forth in SEQ ID NOs:17, 19, and 23. Furthermore, the dependency of claims 51-53, 56, 69, and 108 has been amended in light of the cancellation of claim 49. Finally, claims 51, 60, and 72 have been amended to more particularly point out and distinctly claim the full scope of Applicants' invention. Support for these amendments can be found in the specification at, for example, page 26, lines 26-35. No new matter has been added.

In light of the amendments and the following remarks, Applicants respectfully request reconsideration and allowance of claims 50-56, 60, 69-72, and 108.

Election/Restrictions

The Examiner stated that Applicants' arguments with regard to the restriction requirement were not persuasive, and the requirement was made final. Applicants have canceled

claims 57-59, 61-68, 73-76, and 79-107 without prejudice to future prosecution. Applicants renew their request for withdrawal of the restriction requirement.

Objections to the Specification

The Examiner stated that the specification fails to comply with the sequence rules of 37 C.F.R. §§ 1.821-1.825, because sequences appear on pages 43, 45, and 53-56 without sequence identifiers. Applicants have amended pages 43, 45, and 53-56 to incorporate sequence identifiers, and a corrected sequence listing is submitted herewith. In light of these amendments, Applicants respectfully request withdrawal of the objection to the specification.

Double patenting

The Examiner rejected claims 49, 50, 52-56, and 69-71 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,331,662 (the '662 patent). In addition, the Examiner rejected claims 49 and 56 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/315,515 (the '515 application). Applicants will submit a terminal disclaimer upon an indication that the claims of the present application are otherwise allowable.

Rejections under 35 U.S.C. § 112

The Examiner rejected claims 77 and 78 under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants have canceled claims 77 and 78. Thus, the rejection under 35 U.S.C. § 112, second paragraph is moot.

The Examiner also rejected claims 49-56, 60, 69-72, 77, 78, and 108 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner stated that the specification does not describe the structures or functions of all isolated nucleic acids that comprise SEQ ID NO:1 or SEQ ID NO:2. Similarly, the Examiner

asserted that the specification does not describe any nucleic acid sequences that have 70% identity to SEQ ID NO:11, or that encode amino acid sequences having at least 79% identity with SEQ ID NO:12, and that encode reverse transcriptases. The Examiner further asserted that the specification does not describe any isolated nucleic acids that confer the traits listed in claim 77, which encompasses genes that have yet to be isolated and thus cannot be described.

Applicants respectfully disagree with respect to the amended claims. While ruling that one cDNA sequence does not provide sufficient written description of a genus of cDNA sequences, the Court of Appeals for the Federal Circuit stated the following:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Regents of University of California v. Eli Lilly & Co. 119 F.3d 1559, 1569 (Fed. Cir. 1997)

In contrast to the specification at issue in the Lilly case, the present specification discloses five embodiments of nucleotide sequences that contain a primer binding site at least 95% identical to SEQ ID NO:1 or SEQ ID NO:2 (SEQ ID NOs:1, 2, 17, 19, and 23), nine embodiments of a reverse transcriptase coding sequence at least 70% identical to SEQ ID NO:11 (SEQ ID NOs:11, 17, 19, 20, 21, 22, 23, 29, and 34), and six embodiments of a long terminal repeat (SEQ ID NOs:17, 19, 20, 21, 22, and 23). Thus, Applicants disclose numerous species of the elements within the claims. In addition, the specification provides three embodiments of sequences (SEQ ID NOs:17, 19, and 23) containing (a) a primer binding site that is at least 95% identical to SEQ ID NO:1 or SEQ ID NO:2, (b) a reverse transcriptase coding sequence that is at least 70% identical to SEQ ID NO:11 positioned 3' to the primer binding site, and (c) a long terminal repeat positioned 5' to the primer binding site or 3' to the reverse transcriptase coding sequence. The sequences of these three embodiments fall within the recited range of lengths.

The examples presented above demonstrate that the specification provides an adequate number of species, defined by nucleotide sequence, to describe the claimed genus and to satisfy the written description requirement. The Lilly court recognized, as did its predecessor court in *In re Angstadt*, that not all species need to be disclosed in order to adequately describe a claimed

genus. See, *In re Angstadt* 537 F.2d 498, 502-503 (Cust. & Pat. App. 1970). To require nucleotide sequences for dozens or more species sets a standard that is not an accurate reflection of the law. For example, the Union Oil court held that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.'" See, *Union Oil Company of California v. Atlantic Richfield Company*, 208 F.3d 989, 997 [Fed. Cir. 2000, citing *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)]. By disclosing the nucleotide sequences discussed above, the specification clearly allows persons of skill in the art to recognize that Applicants invented the presently claimed nucleic acids. Thus, the specification meets the legal standard and satisfies the written description requirement. A person of ordinary skill in the art reading Applicants' specification at the time the application was filed would have appreciated that Applicants invented and were in possession of the presently claimed subject matter.

The Examiner also rejected claims 49-56, 60, 69-72, 77, 78, and 108 under 35 U.S.C. § 112, first paragraph, as not being enabled. Specifically, the Examiner asserted that the specification is enabling for SEQ ID NO:1, SEQ ID NO:2, and nucleotide sequences encoding SEQ ID NO:12, but does not reasonably provide enablement for all nucleic acids comprising SEQ ID NO:1 or SEQ ID NO:2, nucleic acid sequences that have at least 70% identity with SEQ ID NO:11, or nucleic acid sequences encoding amino acid sequences that have at least 79% identity to SEQ ID NO:12. The Examiner also stated that the specification does not enable the claimed vectors or the claimed methods, or isolated nucleic acids that confer all of the traits recited in claim 77. Thus, the Examiner alleged that given (1) the breadth of the claims, (2) the unpredictability of the art, and (3) the lack of guidance of the specification, undue experimentation would be required for one skilled in the art to make and use the claimed invention.

Applicants respectfully disagree with respect to the amended claims. While amended claims 50 and 69 cover a number of embodiments, they do include relevant limitations. For

example, amended claim 50 recites a nucleic acid that has a length within a specified range, contains a primer binding site that is at least 95% identical to SEQ ID NO:1 or 2, contains a reverse transcriptase coding sequence, and contains a long terminal repeat. In addition, the recited sequence elements must be arranged in a particular order. Furthermore, claim 69 recites that the reverse transcriptase coding sequence is at least 70% identical to SEQ ID NO:11, or encodes a reverse transcriptase having an amino acid sequence at least 79% identical to SEQ ID NO:12. Thus, the scope of the claims is not inordinately broad.

With regard to the unpredictability of the art, Applicants respectfully submit that a person having ordinary skill in the art at the time the application was filed would have been able to make and use a nucleic acid as recited in amended claims 50 and 69. For example, a person of ordinary skill would have been able to use standard molecular biology techniques to prepare a nucleic acid between about 4,609 and about 12,571 nucleotides in length, wherein the nucleic acid contains a primer binding site, a long terminal repeat, and a reverse transcriptase coding sequence. This is especially true given that Applicants' specification provides (1) five examples of primer binding sites at least 95% identical to SEQ ID NO:1 or SEQ ID NO:2 (SEQ ID NOs:1, 2, 17, 19, and 23); (2) nine examples of reverse transcriptase coding sequences at least 70% identical to SEQ ID NO:11 (SEQ ID NOs:11, 17, 19, 20, 21, 22, 23, 29, and 34); (3) six examples of long terminal repeats (SEQ ID NOs:17, 19, 20, 21, 22, and 23); and (4) three examples of nucleic acids that fall within the recited range of lengths and contain all three elements of the claimed nucleic acids (SEQ ID NOs:17, 19, and 23). Furthermore, retroelement motifs such as long terminal repeats, reverse transcriptase coding sequences, and primer binding sites have been known in the art for years. See, e.g., See, e.g., Grandbastien, "Retroelements in higher plants," *Trends Genet.* 8(3):103-108, 1992; and Boeke and Sandmeyer "Yeast transposable elements" in The Molecular and Cellular Biology of the Yeast Saccharomyces, Vol. 1 (eds. Broach, Jones, and Pringle), pp. 193-261 (Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, 1991; copies enclosed) for descriptions of retroelement sequences such as long terminal repeats. Moreover, reverse transcriptase enzymes have been commercially available for some time. Thus, the art relevant to the amended claims is not overly unpredictable.

Furthermore, Applicants' specification provides sufficient guidance for making and using a nucleic acid that is about 4,609 to about 12,571 nucleotides in length and contains a long terminal repeat, a primer binding site, and a reverse transcriptase coding sequence. See, e.g., Example 1 of Applicants' specification (page 43, line 6 to page 51, line 19). In addition, the specification sets forth examples of such nucleotide sequences in SEQ ID NOS:17, 19, and 23. Moreover, the specification teaches that nucleic acid molecules can be used as primers or probes. See, the specification at page 25, line 34 to page 26, line 15. The specification also teaches that such nucleic acids can be incorporated into vectors and delivered to a host cell. See, e.g., page 26, line 26 to page 28, line 22. In addition, a person of ordinary skill in the art would have appreciated that the presently claimed nucleic acid molecules could be used as, for example, markers for molecular breeding. See, e.g., Purugganan and Wessler (1995) *Mol. Ecol.* 4:265-269; Bhattacharyya et al. (1997) *Plant Mol. Biol.* 34:255-264; Ellis et al. (1998) *Mol. Gen. Genet.* 260:9-19; Flavell et al. (1998) *Plant J.* 16:643-650; and Pearce et al. (1999) *Plant J.* 19:711-717 (copies attached). Thus, the specification and the knowledge of one of ordinary skill in the art provide more than sufficient guidance.

In light of the above, Applicants respectfully submit that the specification would have enabled a person skilled in the art at the time the application was filed to make and use the presently claimed nucleic acid molecules. No undue experimentation would have been required. Applicants note that the rejection of claims 49, 77, and 78 is moot in light of their cancellation. Applicants respectfully request withdrawal of the rejections of claims 50-56, 60, 69-72, and 108 under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 102

The Examiner rejected claim 49 under 35 U.S.C. § 102(b) as being anticipated by Rounsley et al. (GenBank Accession No. B62585). In light of the cancellation of this claim, the Examiner's rejection is moot.

CONCLUSION

Applicants respectfully submit that claims 50-56, 60, 69-72, and 108 are in condition for allowance, which action is requested. The Examiner is invited to telephone the undersigned if such would further prosecution.

Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: December 29, 2003

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